K093636

510(k) Summary

Sponsor: Boston Scientific Corporation
One Boston Scientific Place
Natick MA 01760

Contact Person: Shannon Pettit

Phone Number: 763-494-2833

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DEC 23 2009

Prepared: November 23, 2009

Trade Name: Sterling™ ES MR and OTW PTA Balloon Dilatation Catheters

Common Name: Percutaneous Transluminal Angioplasty Catheter

Classification: II

Product Code: LIT
21 CFR 870.1250

Predicate Devices: Sterling ES Monorail (MR) and Over-the-Wire (OTW) PTA Balloon Dilatation Catheters (K080982; clearance date July 14, 2008)

Device Description

The Sterling ES PTA Balloon Dilatation Catheters consist of a Monorail and an Over-The-Wire catheter designs with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of 0.014" guidewires to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures.

Two radiopaque marker bands (one proximal and one distal), in conjunction with fluoroscopy, enable accurate positioning of the balloon. The working lengths of the balloon catheters are approximately 143 cm.

Indications for Use

The Sterling ES MR and OTW PTA Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The 2.00 mm – 4.00 mm balloon devices are also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Substantial Equivalence

The Sterling ES MR and OTW PTA Balloon Dilatation Catheter design, materials, manufacturing process and intended use are substantially equivalent to the predicate device and other marketed PTA catheters.

Performance Data

The safety and effectiveness of the modified Sterling ES MR and OTW PTA Balloon Dilatation Catheter is demonstrated with design control activities and bench testing on file at Boston Scientific.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Ms. Shannon Pettit
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

DEC 2 3 2009

Re: K093636
Trade/Device Name: Sterling ES Monorail & Over-the-Wire PTA Balloon Dilatation Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: November 23, 2009
Received: November 24, 2009

Dear Ms. Pettit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K093636

Device Name Sterling™ ES Monorail® and Over-the-Wire PTA Balloon Dilatation Catheters

Indications for Use

The Sterling ES Monorail and Over-the-Wire PTA Balloon Dilatation Catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109** **OR** **Over-The-Counter Use**____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093636